

1081188  
JUL 14 2008

### 510(k) Summary

The information below is provided for the Modifications to the Trilogy Radiotherapy Delivery System known as Trilogy with External System Gating Interface, following the format of 21 CFR 807.92.

1. Submitter: Varian Medical Systems  
3100 Hansen Way, M/S e110  
Palo Alto, CA 94304  
Contact Name: Vy Tran  
Phone: 650/424.5731  
Fax: 650/842.5040  
E-mail: [vy.tran@varian.com](mailto:vy.tran@varian.com)
2. Name of the Device: Trilogy™ with External System Gating Interface  
Trade / Proprietary Name: Trilogy™ Radiotherapy Delivery System  
Common or Usual Name: Trilogy™ Radiotherapy Delivery System  
Classification Name: Medical Charged Particle Radiation Therapy System  
21 CFR §892.5050  
Class II  
Product Code: 90 IYE✓

3. Predicate Device to claim substantial equivalence:  
Varian Trilogy Tx Radiotherapy System –K072916

4. Description of the Device:

The Trilogy System modifications enable the export of beam information to external gating devices.

All other features of the Trilogy System and remain as cleared by K033343, K061140, K070094 and 072916.

5. Intended Use Statement

The Trilogy™ Radiotherapy Delivery System is intended to provide stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

6. Indications for Use Statement

The Trilogy™ Radiotherapy Delivery System is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

The External System Gating Interface is indicated for use in exporting beam information to external gating devices.

7. Substantial Equivalence

The submission for the Trilogy™ with External System Gating Interface illustrates substantial equivalence to the predicate device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 14 2008

Ms. Vy Tran  
Corporate Director, Regulatory Affairs  
Varian Medical Systems  
3100 Hansen Way, M/S/ E-110  
PALO ALTO CA 94304

Re: K081188

Trade/Device Name: Trilogy™ with External System gating Interface  
Regulation Number: 21 CFR 892.5050  
Regulation Name: Medical charged-particle radiation therapy system  
Regulatory Class: II  
Product Code: IYE  
Dated: April 25, 2008  
Received: April 28, 2008

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

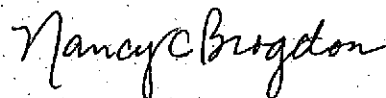
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure



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Palo Alto, CA 94304-1038  
USA  
Tel +1 650 493 4000  
www.varian.com

### Indications for Use Statement

510(k) Number (if known): K081188

Device Name: Trilogy™ with External System Gating Interface

The Trilogy™ Radiotherapy Delivery System is indicated for stereotactic radiosurgery and precision radiotherapy for lesions, tumors and conditions anywhere in the body when radiation treatment is indicated.

The External System Gating Interface is indicated for use in exporting beam information to external gating devices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR § 801.109)

OR Over-the-counter \_\_\_\_\_

[Signature]  
(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number K081188